Safety limits means the limits on process variables associated with those safety class physical barriers, generally passive, that are necessary for the intended facility function and that are required to guard against the uncontrolled release of radioactive materials.

Safety management program means a program designed to ensure a facility is operated in a manner that adequately protects workers, the public, and the environment by covering a topic such as: quality assurance; maintenance of safety systems; personnel training; conduct of operations; inadvertent criticality protection; emergency preparedness; fire protection; waste management; or radiological protection of workers, the public, and the environment.

Safety management system means an integrated safety management system established consistent with 48 CFR 970.5223-1.

Safety significant structures, systems, and components means the structures, systems, and components which are not designated as safety class structures, systems, and components, but whose preventive or mitigative function is a major contributor to defense in depth and/or worker safety as determined from safety analyses.

Safety structures, systems, and components means both safety class structures, systems, and components and safety significant structures, systems, and components.

Service means the performance of work, such as design, manufacturing, construction, fabrication, assembly, decontamination, environmental restoration, waste management, laboratory sample analyses, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

Surveillance requirements means requirements relating to test, calibration, or inspection to ensure that the necessary operability and quality of safety structures, systems, and components and their support systems required for safe operations are maintained, that facility operation is within safety limits, and that limiting control

settings and limiting conditions for operation are met.

Technical safety requirements (TSRs) means the limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility and include, as appropriate for the work and the hazards identified in the documented safety analysis for the facility: Safety limits, operating limits, surveil lance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix.

Unreviewed Safety Question (USQ) means a situation where

- (1) The probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the documented safety analysis could be increased:
- (2) The possibility of an accident or malfunction of a different type than any evaluated previously in the documented safety analysis could be created:
- (3) A margin of safety could be reduced; or
- (4) The documented safety analysis may not be bounding or may be otherwise inadequate.

Unreviewed Safety Question process means the mechanism for keeping a safety basis current by reviewing potential unreviewed safety questions, reporting unreviewed safety questions to DOE, and obtaining approval from DOE prior to taking any action that involves an unreviewed safety question.

Use and application provisions means the basic instructions for applying technical safety requirements.

(b) Terms defined in the Act or in 10 CFR part 820 and not defined in this section of the rule are to be used consistent with the meanings given in the Act or in 10 CFR part 820.

# §830.4 General requirements.

- (a) No person may take or cause to be taken any action inconsistent with the requirements of this part.
- (b) A contractor responsible for a nuclear facility must ensure implementation of, and compliance with, the requirements of this part.

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- (c) The requirements of this part must be implemented in a manner that provides reasonable assurance of adequate protection of workers, the public, and the environment from adverse consequences, taking into account the work to be performed and the associated hazards.
- (d) If there is no contractor for a DOE nuclear facility, DOE must ensure implementation of, and compliance with, the requirements of this part.

#### §830.5 Enforcement.

The requirements in this part are DOE Nuclear Safety Requirements and are subject to enforcement by all appropriate means, including the imposition of civil and criminal penalties in accordance with the provisions of 10 CFR part 820.

#### §830.6 Recordkeeping.

A contractor must maintain complete and accurate records as necessary to substantiate compliance with the requirements of this part.

## §830.7 Graded approach.

Where appropriate, a contractor must use a graded approach to implement the requirements of this part, document the basis of the graded approach used, and submit that documentation to DOE. The graded approach may not be used in implementing the unreviewed safety question (USQ) process or in implementing technical safety requirements.

## Subpart A—Quality Assurance Requirements

# §830.120 Scope.

This subpart establishes quality assurance requirements for contractors conducting activities, including providing items or services, that affect, or may affect, nuclear safety of DOE nuclear facilities.

# §830.121 Quality Assurance Program (QAP).

(a) Contractors conducting activities, including providing items or services, that affect, or may affect, the nuclear safety of DOE nuclear facilities must

- conduct work in accordance with the Quality Assurance criteria in §830.122.
- (b) The contractor responsible for a DOE nuclear facility must:
- (1) Submit a QAP to DOE for approval and regard the QAP as approved 90 days after submittal, unless it is approved or rejected by DOE at an earlier date.
- (2) Modify the QAP as directed by DOE.
- (3) Annually submit any changes to the DOE-approved QAP to DOE for approval. Justify in the submittal why the changes continue to satisfy the quality assurance requirements.
- (4) Conduct work in accordance with the QAP.
- (c) The QAP must:
- (1) Describe how the quality assurance criteria of §830.122 are satisfied.
- (2) Integrate the quality assurance criteria with the Safety Management System, or describe how the quality assurance criteria apply to the Safety Management System.
- (3) Use voluntary consensus standards in its development and implementation, where practicable and consistent with contractual and regulatory requirements, and identify the standards used.
- (4) Describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the criteria of §830.122.

### §830.122 Quality assurance criteria.

The QAP must address the following management, performance, and assessment criteria:

- (a) Criterion 1—Management/Program.
- (1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.
- (2) Establish management processes, including planning, scheduling, and providing resources for the work.
- (b) Criterion 2—Management/Personnel Training and Qualification.
- (1) Train and qualify personnel to be capable of performing their assigned work.
- (2) Provide continuing training to personnel to maintain their job proficiency.